IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF GEORGIA ATLANTA DIVISION

LORENZO BYRD, on behalf of TOMMY L. BYRD, an incompetent adult,

Plaintiff

vs.

UNITED STATES OF AMERICA,

Defendant

NO. 1:20-CV-03090-LMM

PLAINTIFF'S RESPONSE TO GOVERNMENT'S MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

The Government asks this Court to try this case on paper in the form of a summary judgment motion. The Court should reject the Government's attempt to avoid trial on these disputed issues.

Courts across the country reject the Government's argument. For example, in Bak v. Henry Ford Macomb Hosp. Corp., the defendant argued that thrombectomy on patients was "controversial" and plaintiff "was essentially untreatable—even at a major stroke center like Henry Ford-Main—in March 2014." No. 342483, 2019 WL 5681195, at *7 (Mich. Ct. App. 2019). The Court rejected their argument on proximate causation, holding that it was a question of fact for the jury to decide. *Id.* Specifically, the court held that there was no way for the defendant's expert to know what an interventionist would have done "under the precise circumstances presented—after proper imaging studies were performed—and plaintiff was deprived of the opportunity to have such a consultation." *Id.* The fact that the defendant's negligence prevented timely testing to determine whether Plaintiff would have benefited was crucial to the court's opinion. Id. at *8 ("because Bak did not receive the necessary imaging studies ... which was a breach of the standard of care according to plaintiff's expert neurologist ... it is unknown whether Bak had a complete occlusion at that time.").

Like this case, the defendant argued plaintiff's "clinical picture was consistent with a waxing and waning obstruction." *Id.* And even though his NIH Stroke Scale fluctuated "from 0 to 9, and then back to 0," he

was still a candidate for thrombectomy. *Id*. Also like this case, there was a stroke protocol in place which required intervention for the plaintiff. *Id*. at *9. And the court noted that "there is always controversy in literature and differences of opinion with regard to stroke care and treatment." *Id*. In other words, "technology advanced faster than data generated." *Id*. For these reasons, the Michigan appellate court upheld the trial court's denial of defendant's summary judgment motion. *Id*.

Then, in *Myrick v. Hansa*, a California appellate court affirmed a medical malpractice verdict for \$12 million for the failure to diagnose and refer a patient to a stroke center for thrombectomy in 2010. No. A139810, 2015 WL 871082, at *1–2 (Cal. App. 2015). In *Myrick*, the defendant contended that plaintiff failed to present evidence that, if the appropriate consultations were made under the standard of care, "the invasive neuroradiologist would have agreed that plaintiff met the criteria for transfer and for a thrombectomy." Id. at *3. The court rejected the defendant's argument based in part on the evidence that even in 2010, "neurointerventional radiologists were 'very eager' to perform thrombectomies." *Id.* Essentially, the court credited the plaintiff's expert testimony as to whether some evidence existed to support a jury verdict. Id. at *3-4; see also Ruffino v. Archer, No. 3:17-cv-00725, 2018 WL 10152138, at *3 (M.D. Tenn. 2018) (rejecting defendant's motion to strike expert because he had not performed thrombectomy since 2001 and in 2016 patient did not meet stroke guidelines); Devaney v. Irsik, No. 02AP-80, 2002 WL 31057485, at *1 (Ohio Ct. App. 2002)

(malpractice case in 1993 where "all the physicians agreed" that thrombectomy was appropriate for a carotid artery stroke).

NEGLIGENCE

The Government essentially concedes that VA providers breached the standard of care. Specifically, the Government admits that "At no time prior to Nov. 25, 2016, did any medical provider at the Atlanta VAMC suspect that Byrd was having or had a stroke." ECF No. 67-1, at 22 ¶ 127. But even the Government's own expert testified that the VA providers should have suspected stroke by Nov. 22, 2016. Ex. 1, Wright Dep. 128:2–13. Dr. Wright testified that the standard of care required calling a stroke code and getting a CT—neither of which happened. *Id.* at 106:3–15, 130:10–131:1. Because the Government failed to even suspect stroke, Mr. Byrd did not get tests to identify the specific location, timing, or evolution of the stroke. Troublingly, the Government asks this Court to reward its negligence with a dismissal of this case. *See* Ex. 2, Nogueira Dep. 100:22–101:5 (before Nov. 25, 2016, the VA neither diagnosed Mr. Byrd, nor provided any stroke related treatment).

1. The Government failed to follow its own policies.

In fact, upon suspicion of stroke, Atlanta VA providers were required under VA policies in 2016 to perform an NIH Stroke scale and

exclude mimics. E.g., Ex. 3, at USAO11285¹ (t-PA policy); USAO11265 ¶ f(2). Crucially, any inpatient with signs and symptoms consistent with acute ischemic stroke must be evaluated emergently (within 10 minutes) and the stroke team must be activated. Id. at USAO11259 ¶ 2; USAO11264 ¶ 3(a). The Government believes that since the "time is brain" rule has limits—if you wait for enough brain cells to die, you don't have an obligation to treat the patient. Cf. Ex. 4, Kumar Dep. 131:10-18 ("if you let time elapse, then, yeah, you can't do anything."). But that's why providers try to intervene before too much brain tissue dies, causing a permanent disability. Ex. 1, Wright Dep. 70:14-23. As the Government's expert put it: "Time is brain up until the stroke tissue is dead." Id. at 74:10-14; see also Bak, 2019 WL 5681195, at *10 ("Time is of the essence" in stroke care).

The stroke protocol isn't the only protocol the Government providers breached—they also failed to follow the delirium protocol. Ex. 3, at USAO11236–42. Notably, this protocol recognizes that identification of the underlying cause as the "first step" in management of delirium. *Id.* at USAO11237. It uses the acronym "THINK" to identify potential causes—such as a lack of oxygenated blood flow due to stroke.² *Id.*

Records produced by the Government in discovery are bates stamped with the prefix "USAO_BYRD_". To save space, Plaintiff will shorten that prefix to "USAO."

² Incidentally, this protocol contains yet another assessment that the Government failed to do. Ex. 3, at USAO11241; Ex. 2, Nogueira Dep. 47:8–24. This protocol requires a complete delirium workup, which is supported by the Government's

2. The Government breached the standard of care.

Ruling out dangerous pathologies is a basic tenant of medicine that has support from doctors on both sides. Ex. 5, Jabaley Dep. 38:8–11 (providers should rule out life-threatening causes of a patient's presentation); Ex. 6, Yepes Dep. 32:3–6, 32:17–19 (same); Ex. 7, Goracy Dep. 46:3–6 (same); Ex. 1, Wright Dep. 47:7–14 (same). And stroke is a life-and limb-threatening cause that should be ruled out by providers emergently. Ex. 6, Yepes Dep. 44:17–20; Ex. 7, Goracy Dep. 125:2–4; Ex. 1, Wright Dep. 48:12–14, 62:20–22.

One way to rule out stroke is to get imaging. *E.g.*, Ex. 8, Jensen Dep. 164:12–165:8. If they don't get imaging, they don't know whether the patient is bleeding internally, having a stroke, or having a wide range of life-threatening issues. *Id.* at 48:18–25, 42:4–7. The Government's own literature states: "The abrupt onset of focal neurological symptoms is presumed to be vascular in origin until proven otherwise ... Rapid neuroimaging with CT or MRI is recommended to distinguish ischemic stroke from [internal bleeding]." Ex. 3, at USAO14333–34; *see also id.* at USAO14375 ("Emergency imaging of the brain is recommended..."); Ex. 8, Jensen Dep. 38:7–11 (same). And delayed imaging means delayed care. Ex. 4, Kumar Dep. 33:19–34:6.

own literature. Ex. 3, at USAO145630 (Recommendations for neurological assessment and provide the CAM test before imaging). The Government did absolutely no workup. Ex. 3, USAO11241; Ex. 2, Nogueira Dep. 47:8–24.

In contrast to the Government's brief, the literature states that providers need to "make sure that a focal brain lesion that needs immediate attention is not present." Ex. 9, at NTL6873; Ex. 4, Kumar Dep. 48:3–23 (must rule out stroke). In fact, a stroke of the "inferior division of the middle cerebral artery, leading to a Wernicke's aphasia" is one of the known medical causes of delirium. Ex. 9, at NTL6873; see also Ex. 3, at USAO52; USAO11567 (exact type of stroke Byrd had). And if "concern for ischemic stroke and large vessel occlusion exists, a CT scan of the brain with CT angiography or MR with MR angiography should be obtained." Ex. 9, at NTL6873; ECF No. 36-2 (Kumar Report); ECF No. 36-3 (Kumar supplemental Report). Even the DSM5 requires ruling out stroke in a patient with delirium. Ex. 9, at NTL6882, 6887, 6895. See also ECF No. 36-5, at 11 (Morgan Report); Ex. 9, at NTL6924–25 ("Never assume that acute delirium is caused by" psychiatric disease).

In sum, the Government's failure to suspect stroke and immediately activate the stroke protocol was negligent.³

The Government claims that Plaintiffs claims for negligent failure to train and supervise, negligent failure to complete a stroke workup, and negligent failure to maintain continuity of care should also be dismissed. ECF No. 67-2, at 26 n. 10 (citing ECF No. 1, ¶ 5.2(c), (d), (i), and (j)).

However, multiple Plaintiff's experts make it clear that there was a systemic problem in failing to train and supervise the VA's residents. For example, Dr. Morgan's report explains that the likely contributor to the deviation of the standard of care was the failure to train and supervise residents. ECF No. 36-5, at 12–13 (Morgan Report); see also Ex. 4, Kumar Dep. 187–189 (critical of neurology supervision and training); Ex. 10, Morgan Dep. at 89:10–19 (standard of care breached due to communication problems). "Reliance on resident physicians to be

CAUSATION

Had the VA tried to identify the cause of Mr. Byrd's presentation, they would have discovered a stroke, provided him stroke care, including transfer to a facility capable of performing a thrombectomy on him. See ECF No. 36-2 (Kumar report); ECF No. 36-3 (Kumar supplemental report); ECF No. 36-7 (Jensen report).

1. The Government's policies support Plaintiff's causation case too.

Here, the Government fights its own stroke protocol for one simple reason. If it lines up with the standard of care—as Plaintiff's experts opine—then Mr. Byrd should have received a thrombectomy. Ex. 3, at USAO11257–73. By way of background, the protocol was signed and

responsible for performing the examinations on which critical, time-sensitive decisions are made" increases the likelihood of a misdiagnosis. ECF No. 36-5 at 13. Multiple times during Mr. Byrd's care, the VA failed to supervise their residents. Most notably, a first-year resident performed a critical neurological exam on Mr. Byrd on Nov. 22, for which the attending was not present nor did the attending review it until the next day. *Cf.* Ex. 3, at USAO12405 (not noting that the supervisor was present) *with* USAO12384 (same resident: "I have seen and discussed the patient with my Supervising Practitioner Dr. Yepes...").

The failure to complete a full stroke protocol and identify the cause of Mr. Byrd's stroke is also supported by expert testimony and evidence. *E.g.*, ECF No. 36-2, at 7 (Kumar report); Ex. 4, Kumar Dep. 47–48. In fact, once the Government finally diagnosed the fact that Mr. Byrd was having a stroke, they did conduct the workup described, including cardiology, concluding "mechanism is cryptogenic at this point although suspect cardioembolic." Ex. 3, at USAO12344. They ordered trans-thoracic echocardiograms (TTE), carotid dopplers, and telemetry. *Id.* While no Holter monitoring was provided, this was the very care that Plaintiff alleges should have occurred much sooner. *See also id.* at USAO14405 (guidelines recommending cardiac care as a part of stroke workup).

dated in September of 2016 by the director of the VA, and it rescinded a previous version of the protocol, and set a date of automatic review. Id. at USAO11269. Under this policy, Mr. Byrd would have been a "candidate for neurointerventional procedure" under either paragraph of the first or second part of their transfer protocol. Id. at USAO11264. The difference between the two criteria is that one requires a stroke score of greater than or equal to six and the second allows a stroke score of less than six if the patient has a "disabling clinical deficit" like aphasia. Id.; see also Ex. 8, Jensen Dep. 193:7–23 (Jensen testimony this policy).

Knowing that its policies undermine its case, the Government argues that the VA never "fully" implemented them. Yet, in 2016, the VA implemented a system for emergent response to strokes by pager. Ex. 5, Jabaley Dep. 34:1–7. The VA also implemented an emergency stroke activation system and neuroimaging. *Id.* at 34:8–12. If a provider suspected stroke, they were supposed to activate the stroke team. *Id.* at 35:17–21, 36:2–11; *see also* Ex. 3, at USAO11258 (stroke response team includes neurology and imaging team). Next, in response to Plaintiff's

The Government attached other policies—disclosed for the first time at summary judgment—that it claims was in effect only with the signature of the VA's Medical Director. *E.g.*, ECF No. 67-8, at 50 (Resident and medical student supervision policy). Moreover, the Government also provided stroke protocol in response to Plaintiff's request for stroke protocols that "were in effect or used at Atlanta VA during November 2016." Ex. 11, Def. Resp. Pls. 1st Set of Requests for Production, 1st Supp. at 16 ¶ 40 (Jun. 7, 2021). After discovery, the Government supplemented this response claiming that the VA did not have "clear stroke protocols," but it "produced documents that it could identify that were executed in or around 2016." *Id.* Notably, if the 2016 stroke protocol was not "in effect or used" in 2016, the Government failed to produce the rescinded policies that were in place.

request for production asking for stroke posters at VAMC in 2016, the Government produced posters showing the implementation of those policies. Ex. 3, at USAO14308–09. Unsurprisingly, the poster language mirrors the policies the Government claims were not "implemented." *Compare id.* at USAO14309 *with id.* at USAO11259.

Then, the Government's expert, Dr. Wright, confirmed that the phone number in the 2016 policy for transfer of patients for mechanical thrombectomy was the correct transfer number for Emory. *Compare id.* at USAO11264 ¶ (2)(a)(1) *with* Ex. 1, Wright Dep. 170:20–171:12 ("I'm seeing the accurate phone number."), Ex. 6 to Wright Dep. (showing the same phone number as found in the VA's 2016 policy). *See also* Ex. 1, Wright Dep. 32:14–22, 30:5-6 (Emory University Hospital is a tertiary referral center), 42:20–23 (From the Emory University Hospital end, they accepted referrals from the VA for stroke patients in 2016).

Essentially, the Government asks this Court to dismiss its policies and this case based on self-interested testimony from its doctors. *See Simons v. Conn*, 260 S.E.2d 402, 404 (Ga. Ct. App. 1979) (error in granting summary judgment based on a malpractice defendant's self-serving affidavit); *A.M. v. Saul*, No. 4:19cv00011, 2021 WL 746012, at *5 (W.D. Va. 2021) (same). The Court should reject such an invitation.

2. The medical science supports Plaintiff's causation case.

There's good reason the Government's policy makes Mr. Byrd a candidate for transfer. Because Mr. Byrd's stroke was so proximal and

that his MCA was straight (or lacked tortuosity), Dr. Jensen testified that it would have been "very suitable" to remove it with suction or a stent retriever. Ex. 8, Jensen Dep. 104:2–14; *see also* Ex. 1, Wright Dep. 36:17–37:12 (both types used in 2016). And this stroke was treatable using the tools available in 2016. Ex. 8, Jensen Dep. 185:1–7; Ex. 1, Wright Dep. 181:11–13 (radiographers able to reach the M2).

Both hospitals that Mr. Byrd could have been transferred to were capable of providing this treatment. See ECF No. 67-1, at 7 ¶ 28 (admitting that both Grady and Emory Hospitals capable of performing thrombectomies in 2016). For example, Emory University Hospital—less than three miles away—has been a comprehensive stroke center⁵ since at least 2007. Ex. 1, Wright Dep. 26:7–21. Since 2004, it accepted transfers of patients from the Atlanta VA, including stroke patients. Id. at 27:8–20, 32:14–22. And in 2016, University Hospital performed MCA thrombectomies. Id. at 34:2–7, 37:6–12. Similarly, Grady was also a comprehensive stroke center. See Ex. 2, Nogueira Dep. 252:5–22; Ex. 1, Wright Dep. at 135:1–13. Of course, Grady has been doing M2 thrombectomies since 2004. Ex. 2, Nogueira Dep. 136:9–20.

⁵ See Joint Commission Stroke Certification Comparison, available at https://www.jointcommission.org/-/media/tjc/documents/accred-and-cert/certification/certification-by-setting/stroke/dsc-stroke-grid-comparison-chart-42021.pdf

THROMBECTOMY

The Government acts as if, in 2015, the medical community first discovered the effectiveness of thrombectomy. In fact, the 2015 thrombectomy studies had to be suspended because they were so effective. Ex. 2, Nogueira Dep. 151:20–152:6. Stated another way, it would have been unethical to continue to randomize patients into a treatment without thrombectomy. Id. Glossing over this crucial fact, the Government touts three studies from 2013 claiming that thrombectomy was not appropriate for stroke patients. ECF No. 67-2, at 7. In actuality, the medical community recognized those studies were limited by the fact that the stroke was not confirmed, and the treatment was delayed. Ex. 3, at USAO145609 (conclusion of Government's literature). So really, the Government's studies stand for the proposition that the VA's delayed treatment and failure to image caused injury.

That's because, by late 2016, providers had a large trove of data on M2 clots specifically. Ex. 8, Jensen Dep. 84:19–85:5. Looking at that data, you find that patients who have thrombectomies on M2 clots *actually do better* than patients with M1 clots. *Id.* at 85:25–86:23.

1. By 2016, thrombectomy was widely practiced and heavily supported in the literature.

As a result of the literature, thrombectomy was widely used by medical providers in patients like Mr. Byrd. For example, Emory University Hospital (UH) was performing thrombectomies in 2016. Ex. 1,

Wright Dep. 34:2-7, 37:6–12 (same). In fact, the Government's expert testified "I would be surprised if no M2 thrombectomy had ever been performed prior to 2016" at Emory. *Id.* at 39:12–40; *see also id.* at 40:24–41:7 (Dr. Wright testifies that Emory was capable of performing M2 thrombectomies in 2016), 42:16–23 (Emory capable of performing CTAs and accepting stroke patients). As for Plaintiffs experts, the majority (80%) of Dr. Jensen's thrombectomy practice targets MCA strokes. Ex. 8, Jensen Dep. 118:24–119:7. Similarly, Dr. Kumar sees more thrombectomies than t-PA in stroke patients. Ex. 4, Kumar Dep. 35:16–23, 36:13–14 (in the first half of 2021, he's been involved in ~100 thrombectomies), 37:19–38:11 (numbers for 2016). Of those thrombectomies performed in 2016, for Dr. Kumar, twenty percent were M2 thrombectomies. *Id.* at 38:15–39:8; *see also id.* at 76:5–25 (M2 Thrombectomies were performed long before 2016), 79:20–80:23 (same).

Historically, the 2013 Stroke Guidelines recognize that the "number of options for endovascular treatment of ischemic stroke has increased substantially over the past decade." Ex. 3, at USAO14387. These devices have been approved for thrombectomy by the FDA since 2004.6 *Id.* at USAO14387, 89. And by 2013, these procedures were reimbursed by Medicaid and Medicare. *Id.* at USAO14388. The guidelines

The indications for use of the FDA approved devices did not place the arbitrary limitations the Government places on thrombectomy. *E.g.*, FDA 510k Summary (Dec. 2007), accessed on Sept 30, 2021, https://www.accessdata.fda.gov/cdrh_docs/pdf7/K072796.pdf; see also Ex. _, USAO14387–88 (discussion of FDA approval).

actually provided a "stamp of approval" for thrombectomy. Ex. 4, Kumar Dep. 71:18–72:7; but see Bak, 2019 WL 5681195, at *9 ("Technology advanced faster than data generated.").

Of course, the Court must look not only at the individual situation when considering the guidelines, but the Court should look at what the studies specifically say about M2 thrombectomies. Ex. 8, Jensen Dep. 71:4–15. For example, start with the Government's own literature. One study produced by the Government shows "Patients with M2 occlusions are considered appropriate candidates for [thrombectomy] by most respondents in this survey, especially by those performing end-vascular therapy more often and those in high volume centers." Ex. 3, at USAO14580 (survey of 607 doctors). This study explains that the reason M2 patients are not in the guidelines is they are excluded from trials. *Id.* at USAO14585. It concludes that the guidelines should revise their recommendations. *Id.* at USAO14587.

Another Government study examined thrombectomy in M1 through M4 strokes between 2012 and 2017. Id. at USAO145621; see also Ex. 9, at NTL17883 (Government expert's study from 2013–2017 on thrombectomy, including M2). Then, the Government's own expert published a paper on the thrombectomies he performed between 2015–2016 in "minimal symptom" (including M2) patients with a stroke score less than or equal to five. Ex. 9, at NTL17784. He separated them into a thrombectomy group and medical therapy group. Id. Patients were further eligible for thrombectomy if they deteriorated—with deterioration

defined to include aphasia. *Id.* He found M2 thrombectomy 100% effective. *Id.*; see also Ex. 2, Nogueira Dep. 191:15–25.

Similarly, Plaintiff's studies show that M2 thrombectomies are effective. For example, one looked at M2 thrombectomies between 2008 and 2016. Ex. 9, at NTL17654–55. It concluded: "thrombectomy of the M2 segment is as safe as thrombectomy of the M1 segment." *Id.* at NTL17659. Another study from 2014 concluded, "M2 occlusions should be given the same consideration as M1 occlusions." *Id.* at NTL17777; NTL17779–80 ("these patients should be treated with the same vigor as those with M1 occlusions."); NTL6980 (same from 2010).

Multiple other studies conclude the same (Ex. 9):

- NTL17682 (between 2011-2013, M2 thrombectomies were as safe and more beneficial than M1 thrombectomies);
- NTL17697 (2011-2012 study showing the same);
- NTL17728 (same);
- NTL17721 (study on M2 strokes from 2012–2016);
- NTL17709 (study showing patients with proximal M2 strokes benefit from thrombectomy);
- NTL17714 (same);
- NTL17743 (study showing effectiveness in 2013–2014);
- NTL17687 (meta-analysis of 15 studies from 2004-2016 showing the same);
- NTL17704 (meta-analysis of 8 studies from 2010-2017 showing successful M2 thrombectomies).

As a final example, one study of M2 thrombectomies between 2012–2015 showed that those patients had *three times* better outcomes than the "best medical management," even accounting for age, stroke score,

and time from last known well. *Id.* at NTL17771. This study also found no difference in hemorrhage risk of thrombectomy.⁷ *Id.*

While these studies compare patients given thrombectomy over basic stroke care, Mr. Byrd received **no** stroke care. ECF No. 67-1, at 22 ¶ 127. The importance of basic stroke care is underscored in one of the Government own studies, which compared thrombectomy patients to medical therapy without thrombectomy. It found that 77% of medical therapy patients achieved functional independence. Ex. 9, at NTL17784 (compared to 100% independence with thrombectomy). So, even basic medical care without thrombectomy would have helped Mr. Byrd.

2. Mr. Byrd's stroke was not a "low severity" stroke.

The Government argues that Mr. Byrd's injury was a "low severity" stroke. This is factually wrong. For example, the Government took the deposition of Tommy Byrd. But it had to cut the deposition short due to Mr. Byrd's inability to understand even basic questions. *See generally* Ex. 12, Tommy Byrd Dep. 1–22.

Ignoring the facts, Government bases its argument on an NIH Stroke Score. Of course, it skirts past the fact that the *VA never*

The Government complains that thrombectomy—like all medical procedures—has risks associated with it. Ex. 8, Jensen Dep. 50:6–25 (thrombectomy minimally invasive). However, studies show that there are "no significant differences in occurrence of symptomatic intracerebral hemorrhage or other safety aspects" between M1 and M2 thrombectomies. Ex. 9, at NTL17672; NTL17675 (showing other studies were consistent with the results found in this study); NTL17682 (another study showing the same between 2011-2013); NTL17777 (2014 study showing M2 thrombectomies had "significantly less hemorrhage.").

performed that test on Mr. Byrd. Ex. 8, Jensen Dep. 131:5–7, 145:19–146:14 (discussing the lack of NIH testing); Ex. 7, Goracy Dep. 115:18–25 (neither stroke scale nor stroke team called); Ex. 2, Nogueira Dep. 102:16–21 (same). Essentially, the Government asks this Court to give it the benefit of its negligence. *McKellips v. St. Francis Hosp. Inc.*, 741 P.2d 467, 474 (Okla. 1987) ("Health care providers should not be given the benefit of the uncertainty created by their own negligent conduct."); see also Gardner v. Pawliw, 696 A.2d 599, 614 (N.J. 1997).8

2.1. Experts on both sides retrospectively gave Mr. Byrd a stroke score of at least six.

Even then, the Government's expert retrospectively scored Mr. Byrd with an NIH Stroke Score of six (6). Specifically, on Nov. 22—the very date where Dr. Jensen testifies the large stroke occurred—the Government expert's score meets the cutoff. Ex. 1, Wright Dep. 103:6—18; ECF No. 40, at 6 (Dr. Wright's report); Ex. 3, at USAO11264 (Gov't policy). And the Government concedes that this was the minimum "score for **strongly recommended** thrombectomy in 2016." ECF No. 67-2, at 33 (Gov't brief) (emphasis added).

Similarly, Plaintiff's experts opine that the minimum score would be at least six. *E.g.*, Ex. 8, Jensen Dep. 189:1–190:1; ECF No. 36-3, at

These cases were decided under the Restatement of Torts 323, which Georgia has adopted. E.g., Rymer v. Polo Golf & Country Club Homeowners Ass'n, Inc., 780 S.E.2d 95, 102 (Ga. Ct. App. 2015). Indeed, VA medical malpractice claims are a form of negligent undertaking. Ingham v. Eastern Air Lines, Inc., 373 F.2d 227, 234 (2d Cir. 1967) (citing United States v. Brown, 348 U.S. 110 (1954)).

3–4 (Kumar report). But vitally, a retrospective reconstruction will never be as detailed as the full exam. E.g., Ex. 8, Jensen Dep. 145:19–146:14. Here, a quick look at the NIH Stroke Scale itself shows how detailed the examination would have been—and how a cursory physical exam is no substitute. Ex. 9, at NTL17789–NTL17796 (full stroke scale); Ex. 1, Wright Dep. 83:22–25 (authenticating stroke scale). The patient must identify pictures (Ex. 9, at NTL17793, 95) and speak specific words (id. at NTL17794, 96). A physical exam requires specific motions, movement, and instructions. E.g., id. at NTL17790 ¶¶ 5–6.

The Government relies on the records to retrospectively score Mr. Byrd, but basic questions—such as Mr. Byrd's age—were not asked. Compare Ex. 6, Yepes Dep. 87:22–88:3 ("we do not ask age") with Ex. 9, at NTL17789 ¶ 1b (NIH Stroke Scale requiring month and year of age asked). The NIH Stroke Scale is very precise—in its own words, "there is no partial credit for being close." Id. Or as the Government's expert puts it: "the lack of a neurologist or the lack of a stroke team limits my ability to figure out what the stroke — when the stroke occurred." Ex. 1, Wright Dep. at 100:2–5; see also id. at 130:10–19 (medical record simply will not reflect all of the neurologic deficits—deficits that a proper stroke workup can identify).

2.2. Even a stroke score below six requires intervention.

But even a "low severity" stroke requires intervention if the patient has aphasia. Ex. 8, Jensen Dep. 167:11–16, 99:1–100:2. There's an exception because "the NIH Stroke Scale is woefully incomplete for us

and is a difficult tool when you're trying to pick up subtle neurologic deficits." Ex. 1, Wright Dep. 80:20–23 (Gov't expert). You can have low scores but have "significant functional problems." *Id.* at 81:15–20.

This exception for aphasia is found in multiple places. For example, take the Government's own policies. E.g., Ex. 3, at USAO11264 ¶ 2(a.2) (describing aphasia as a "disabling clinical deficit" and an exception for thrombectomy). Also, in the Government expert's own studies, he makes an exception for aphasia. See ECF No. 67-10, at 26-27 ("Inclusion criteria"); see also Ex. 9, at NTL17784 (Dr. Nogueira's study defines deterioration from a "minimal stroke severity" to include aphasia). In another study of patients from 2008–2016, the "significant" number of M2 patients had NIH scores of one (1) to four (4). Ex. 9, at NTL17660. Here's what the authors said: "a low NIHSS score should not exclude patients from mechanical thrombectomy." Id.; see also id. at NTL17771 (M2 thrombectomy three times more effective than best medical management even accounting for NIH score); Ex. 3, at USAO14384 (providers should not withhold treatment from patients with low stroke scores, but with disabling deficits, because those patients will deteriorate); Ex. 9, at NTL17648 (study of patients with NIH score greater than or equal to four or if aphasia was present).9

In contrast, there's a study of patients between 2012 to 2016, providers found that thrombectomy was more effective in M2 patients with a stroke score below 15. Ex. 9, at NTL17722–24.

Lastly, NIH Stroke Scale mentions aphasia *thirteen (13) times* in an eleven (11)-part test. *See* Ex. 9, at NTL17789–92. In sum, aphasia is so disabling that the literature and policies require treatment.

2.3. It's not the size of the vessel that matters, but where the blood flows.

The Government's focus on the size of the vessel wholly misses the point. Where the blood is flows is most important. Ex. 8, Jensen Dep. 101:16-102:8. If you have a smaller vessel flowing to the area of speech comprehension, that disability will still be significant. ¹⁰ *Id.* at 102:9–10. Because the clot blocked the end of the M1 artery, the M2 did not appear on imaging and, so, a provider cannot tell the size of the M2 vessel that Mr. Byrd's stroke blocked. *Id.* at 102:13–104:8; 226:18–227:3 (because providers failed to get imaging, you can only tell the location—inferior vs. superior—not the size of the blocked vessel).

Similarly, the size (or dominance) of the occluded vessel doesn't dictate whether it's a "large vessel occlusion" necessarily. For proximal M2 occlusions—like Mr. Byrd's—the community views them as an extension of the M1.¹¹ Ex. 8, Jensen Dep. 98:3–25; 214:1–9 (Society of Neuro-interventional Surgery considers proximal M2 strokes as large vessel).

The Government sometimes conflates dominance of the vessel for superior/inferior vessels. *E.g.*, ECF No. 67-2, at 7 (citing Jensen). In medicine, inferior does not mean non-dominant; instead, it means "situated below." Inferior, Merriam-Webster Medical Dictionary, https://www.merriam-webster.com/dictionary/inferior#medicalDictionary (last visited Sep. 28, 2021).

The literature shows thrombectomy is more effective in proximal occlusions. *E.g.*, Ex. 9, at NTL17709.

This is consistent with the Government's literature on the matter. *E.g.*, Ex. 3, at USAO145621 (Study design defining large vessel occlusion as including M1, M2, M3, and M4 arteries). In fact, the Government's expert published a paper on the M2 thrombectomies he performed on his patients between 2014–2016, calling them large vessel occlusions. Ex. 9, at NTL17784; *see also* Ex. 8, Jensen Dep. 34:4–10, 49:1–7; Ex. 2, Nogueira Dep. 188:8–13 (LVO includes M2 occlusions); Ex. 4, Kumar Dep. 60:18–61:16 (literature describing Byrd's stroke as LVO).

But regardless, the studies show that compared with patients with M1 and dominant M2 occlusions, "patients with occlusions of the non dominant M2 branch had better functional outcomes." Ex. 9, at NTL17672–73 (also noting that these results were consistent with other studies); see also id. at NTL17745 (study from 2013-2014 noting no difference in outcome between inferior vs superior division M2).

3. The Government wants the benefit of its negligence when it comes to last known well.

The last known well is relevant when you *don't* have imaging. Ex. 8, Jensen Dep. 56:20–59:11. Instead, if you have the imaging that shows "their particular brain has great collateral circulation, they're not infarcted that tissue yet, [then] we're going to pull that clot out." *Id.* at 56:23–57:8. In fact, the imaging determines whether there's a mismatch between the ischemia and the infarct—that is large area of ischemia caused by a small area of stroke. *Id.* at 39:1–10. In this case, the Government's negligence prevented the necessary imaging for Mr.

Byrd. *E.g.*, Ex. 4, Kumar Dep. 191:7–16 (the failure to gather data prevents thrombectomy). But based on the delayed imaging, Dr. Jensen opined timely intervention would have minimized or eliminated Mr. Byrd's deficits. ECF No. 36-7, at 11 (Jensen report). And the Government's literature underscores the point about timely intervention: "Early after onset, the penumbra rapidly achieves maximum volume, whereas the core is minimal, re-

sulting in a pronounced 'ischemic mismatch.' Later, as time elapses, the continued blood flow insufficiency [causes the] reduction of the mismatch." Ex. 3, at USAO14594; see also Ex. 6, Yepes Dep. 36:11–13 (for stroke, every minute counts).

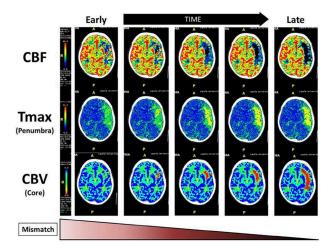


Figure 1: USAO14594

3.1. A retrospective last known well puts Mr. Byrd's stroke on Nov. 22, 2016.

Like the NIH Stroke Score, Plaintiff only has an incomplete record to re-construct the last-known well. Ex. 8, Jensen Dep. 163:8–24, 230:1–22, 126:19–2. Dr. Jensen testified that based on the medical records, the last known well for Mr. Byrd for the purpose of thrombectomy was on Nov. 22, at 10:48am. *Id.* at 115:9–116:24. Dr. Kumar agreed.

Ex. 4, Kumar Dep. 148:2–12.¹² The lack of testing also prevents experts from detecting how many transient attacks occurred before the stroke on Nov. 22, 2016. Ex. 8, Jensen Dep. 126:19–127:17.

Plaintiff's experts opined that Mr. Byrd woke up from surgery, experienced delirium that resolved, but then Mr. Byrd had an "acute change in mental status" on Nov. 22, 2016. And the VA's own records describe this timeline best: "patient was of normal cognition for the past few days, A&Ox3 with plans to discharge today. ... this current mental status is an acute change." Ex. 3, at USAO12408. This timeline also fits the Government's admission that Mr. Byrd's initial "symptoms were resolved by giving him medication." Ex. 13, Gov't Initial Disclosures, 1st Supp, at 3 (June 7, 2021); see also Ex. 8, Jensen Dep. 150:12–25 (Byrd cannot complete physical or occupational therapy with aphasia or the other symptoms noted in subsequent records).

In contrast, the Government offers only self-interested statements. Here, the VA doctors argue that the last known well was before surgery. If Mr. Byrd was exhibiting delirium or other stroke symptoms when he woke up from surgery, did the VA providers incorrectly document their records? In fact, the Government swore in response to an interrogatory that the United States was not aware of any inaccurate or incomplete information in Mr. Byrd's medical records. Ex. 14, Gov't

The Government argues that Plaintiff's expert conceded last known well was prior to Mr. Byrd's surgery—the exact opposite happened in deposition. *E.g.*, Ex. 4, Kumar Dep. 104:13–105:4 ("Q. Well, in my hypothetical, his last known normal was prior to surgery. ... A. I don't think I agree with your hypothetical...").

Resp. Pls. Interrogatories, at 4 (#7); see also Ex. 15, Gov't Resp. Pls. Interrogatories, 1st Supp, at 5–6 (supplement: "Defendant is still unaware of any errors in the VA medical records for Plaintiff."). And before his stroke on Nov. 22, if his symptoms didn't resolve, why did the Government want to discharge him that day? See e.g., Ex. 3, at USAO12430 (from the night before the stroke: discharge home); USAO12423 (same from PT); USAO12422 (same from occupational therapy).

The Government argues that Mr. Byrd was being discharged to supervised care, so that means he was not well. Setting aside that by "supervised care," they mean his family, ¹³ the VA's treatment after diagnosing Mr. Byrd undercuts this argument. After diagnosis on Nov. 25, the VA kept him in the hospital until Dec. 19. Ex. 3, at USAO11657. On Dec. 19, they transferred him to PruittHealth Brookhaven. Ex. 9, at NTL5128 (and discharged from Pruitt in March 2017). At minimum, this means that diagnosing stroke patients matters.

3.2. The Joint Commission definitions are no defense.

The Government's reliance on Joint Commission definition of last known well is misplaced. First, the definition—and the Government's own policies—place the onus on the Government to document the last known well. Ex. 3, at USAO146212; USAO11259 (treating provider is

See Ex. 3, at USAO12423 (At 10:40 am: "PATIENT IS CLEARED FROM A PT STANDPOINT TO DISCHARGE HOME"); see also Ex. 16, L. Byrd Dep. 35:7–11 (Doctor tells Lorenzo Byrd that his dad is "up for discharge" home.).

responsible for documenting "time of onset of symptoms."). Here again, the Government asks for the benefit of its negligence.

Second, this definition identifies the "time prior to hospital arrival." Id. at USAO146212 (emphasis added). That's because inpatients are within the custody of the hospital and there should be no need to guess at their history. In any case, the definition states, if the stroke symptoms resolve—like in Mr. Byrd's case—that resets the clock. E.g., id. at USAO146213 (if numbness resolves two days ago, and new symptoms start at 0700, then 0700 is the last known well).

Third, for the purposes of determining the "last known well," the Government attributes every symptom under the sun to stroke. *E.g.*, ECF No. 67-2, at 37 ("restlessness"). But if "restlessness" is sufficient to prevent reset of the last-well-known clock, it should have been sufficient to call the stroke team. Yet, the Government freely concedes that the VA did not even consider stroke. ECF No. 67-1, at 22 ¶ 127.

In summary, thrombectomy has been shown by multiple studies—including the Government's own literature—to prevent Mr. Byrd's disability. The Government had two clear opportunities to intervene. After his surgery, Mr. Byrd had sudden and acute delirium, yet the VA ignored the troubling neurological causes. And on Nov. 22, where Mr. Byrd "was of normal cognition for the past few days, A&Ox3 with plans to discharge today. ... this current mental status is an acute change." Ex. 3, at USAO12408. In both instances, the VA failed its patient.

CONCLUSION

The Court should deny the Government's request to avoid a trial on disputed issues.

Respectfully Submitted,

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CERTIFICATE OF SERVICE & COMPLIANCE

By my signature below, I certify that this pleading was prepared using Century Schoolbook at 13-point size. Further, I certify that a copy of this pleading, Plaintiff's Response to Government's Motion for Summary Judgment, has been sent to the following on September 30, 2021 via the Court's CM/ECF notice system.

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